

REMARKS

Cancelled Claims

Claims 14-18 and 20 are cancelled without prejudice. The Applicant maintains the right to prosecute such claims in a follow-on continuing application.

Claims 19, 21, and 22

Applicants acknowledge the Examiner's response to traverse of restriction of claims 19, 21/19, and 22/19. Claims 19, 21/19, and 22/19 remain withdrawn subject rejoinder for being dependent from an allowable product claim. Claim 21 is amended to delete the reference to claim 20 since the latter has been cancelled. Claim 22 is amended to depend from claim 21.

Independent Claims 1 and 23

Claim 1 is directed toward a patch including a breathable layer, a barrier layer, a solid layer containing an effective amount of a volatile agent, and a removable release liner. Claim 1 is amended to include the element of "adhesive between adjacent sides of the solid layer and the barrier layer." Support for this amendment may be found in the application at Figure 1; page 8, lines 4-20; Example 1 (page 10); and Example 2 (pages 10-11).

Claim 23 is amended into the form of an independent claim that includes the elements of former claim 1; the claim has not been narrowed from its original scope.

Patentability of Claim 1

A. Prior Art Rejections

Claim 1 stands rejected under 35 U.S.C. §102(b) as being anticipated by Fischel-Ghodsian (U.S. Patent No. 5,071,704). The amended claim, however, is patentable because Fischel-Ghodsian fails to teach or suggest the element of "adhesive between adjacent sides of the solid layer and the barrier layer" as required by the claim.

Fischel-Ghodsian teaches a controlled release device that has a diffusion rate limiting membrane, a reservoir layer, and an impermeable backing layer (see Figure 1). Fischel-

Ghodsian, however, provides no teaching or suggestion that adhesive exists between the reservoir layer and the impermeable backing layer. The reference states that

“For controlled release devices in which the *reservoir layer does not provide the necessary ‘tacky’ surface* for adhering to the impermeable backing layer and the diffusion rate limiting layer, it is desirable to *provide a clip* or other component for securing the layers of the device together. This component may be a miniature clip . . . or a *small amount of adhesive . . . applied to the edges*. Alternatively, the laminate layer *edges may be secured by heat or solvent sealing techniques*.” (column 5, line 63 through column 6, line 6)

In summary, Fischel-Ghodsian teaches four ways of binding the reservoir layer and the impermeable layer: (i) the reservoir layer itself is tacky; (ii) using a clip to bind the layers; (iii) using adhesive applied to the *edges*; or (iv) using heat or solvent sealing techniques to seal the edges. There is no teaching or suggestion anywhere in Fischel-Ghodsian of using “adhesive *between adjacent sides* of the solid layer and the barrier layer” as required by claim 1.

Therefore, Fischel-Ghodsian cannot anticipate claim 1.

Neither is claim 1 obvious. The invention of claim 1 advantageously expands the types of solid layer formulations that may be utilized in a patch without the need for a clip or edge binding. An adhesive attaches a side of a solid layer to a side of a barrier layer. If one were to follow Fischel-Ghodsian in which the solid layer is formed on the barrier layer, an adhesive would be impractical. To apply an adhesive layer to the barrier layer, followed by a liquid mixture on top of the adhesive layer, would permit intermixing of the adhesive and liquid mixture; this may cause contamination of the reservoir layer or limit the ability of the adhesive to bind the reservoir layer and impermeable layer together. Moreover, adhesive mixed in the solid layer may adversely affect the diffusion rate of the volatile agent. A method taught by the Applicant for making the invention of claim 1 involves applying the liquid mixture to the breathable layer. This avoids the problems and limitations of the prior art. The volatile containing liquid cools and forms on the breathable layer. Adhesive can then be advantageously used in between the cooled solid layer and the barrier layer.

Fischel-Ghodsian only teaches a reservoir layer being formed on the impermeable layer directly (see column 9, lines 40-42; column 10, lines 12-14; column 10, lines 47-50; column,

lines 8-12). As well, Fischel-Ghodsian requires that the reservoir layer itself be tacky. Otherwise, a separate clip or binding agent to bind the edges of the breathable layer and barrier layer together is required. Therefore, Fischel-Ghodsian fails to contemplate, consider, or suggest the present invention. Indeed, using the techniques of Fischel-Ghodsian, one skilled in the art is limited in patch production to either (i) using only reservoir forming liquids that are sufficiently tacky to attach to the barrier layer, or (ii) using a clip or other edge binding technique if a reservoir forming liquid is not sufficiently tacky. In contradistinction, the invention of claim 1 may be produced from a liquid that need not stick to the typically smooth barrier layer. The patch can be completed without the clips or other binding techniques taught by Fischel-Ghodsian.

B. Claims Dependent from Claim 1

Claims 2, 3, and 6-13 also stand as being anticipated by Fischel-Ghodsian. Since the claims all depend from allowable claim 1, however, they are all patentable over the cited art.

Claims 4, 5, and 24 stand rejected as being obvious over some combination of Fischel-Ghodsian, Fujita (U.S. Patent No. 5,928,661), and Sweeney (UK Patent Application No. GB 2260494A). The claims, dependent from claim 1, are patentable, however, because none of the references, alone or in combination, teaches the required element of "adhesive between adjacent sides of the solid layer and the barrier layer"

As discussed earlier, Fischel-Ghodsian does not teach the required adhesive of claim 1. Fujita is directed toward a formulation for a controlled release composition. The patent mentions that the composition may be used in combination with various substrates (see column 5, lines 8-45). The patent does not teach (i) a patch or (ii) using adhesive, as required by claim 1.

Sweeney is directed toward a gel type fragrant composition. The composition may be prepared in trays, or in molds to form gel blocks (page 16, lines 3-18). Sweeney does not teach (i) a patch or (ii) using adhesive, as required by claim 1.

Thus none of the cited art teaches a patch with adhesive between adjacent sides of a solid layer and a barrier layer, as required by claim 1. Thus a prima-facie case of obviousness cannot be established for claim 1. Claims 4, 5, and 24 depend from claim 1, and thus are not obvious for substantially the same reasons.

Patentability of Claim 23

Claim 23 stands rejected as obvious in light of Fischel-Ghodsian. The claim is patentable, however, because none of the cited art, alone or in combination, teaches or motivates the use of a “solid layer . . . made by applying a liquid mixture onto the breathable layer” as required. The office action concedes that Fischel-Ghodsian does not expressly teach the limitation of making a solid layer by applying a liquid mixture onto the breathable layer of the device” (see office action page 5).

The action states that the limitation of claim 23 is obvious since “[o]ne of ordinary skill in the art would have been motivated to modify the process of Fischel-Ghodsian in any order for the convenience and individual manufacturing preference” (see *id.*). But claim 23 is not merely a different ordering of steps as taught by Fischel-Ghodsian. Fischel-Ghodsian entirely lacks a teaching of the act of applying a liquid mixture to a breathable layer to form the volatile agent containing solid layer. As such, the solid layer so made is not taught or suggested by the cited art. Thus Fischel-Ghodsian must rely upon clips, binding techniques, or sufficiently tacky solid layers. The nonobvious patch of claim 23 should be allowed.

If the examiner is relying upon her own knowledge for the missing claim limitation, the Applicant respectfully requests that the examiner prepare an affidavit pursuant to 37 C.F.R. §1.104(d)(2) to support such a rejection.

New Claims 25-32

New claims 25-32 are added to provide further dependent claims from claims 1 and 23.

Specifically, claim 25, dependent from claim 23, adds the limitation of “adhesive between adjacent sides of the solid layer and barrier layer.” As such the claim is patentable for the same reasons as claims 1 and 23.

Claim 26, dependent from claim 23, is supported by the application at page 9, lines 13-19. Claims 27-30 are substantially the same as claims 2-5, but dependent from claim 23. Thus, these claims are allowable for substantially the same reasons as claim 23.

Claims 31 and 32 find support in the application at page 7, lines 8-20. Being dependent from claims 23 and 1, respectively, claims 31 and 32 are patentable for the same reasons that the independent claims are patentable. As well, the claims are also patentable because the cited art

does not teach a breathable layer that includes a non-woven fabric having cellulose fibers and resin, as required by claims 31 and 32.

Conclusion

For the foregoing reasons, among others, the Applicant respectfully requests consideration and allowance of all pending claims. The Applicant also requests the courtesy of a telephone interview with the undersigned if the Examiner believes such communication would expedite prosecution of the application.

Respectfully submitted,



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